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Supreme Court, U.S.
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No. 95-1323

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

BARBARA MITCHELL, *et al.*,
Petitioners,

v.

COLLAGEN CORPORATION,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

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BRIEF IN RESPONSE TO THE PETITION

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QUESTIONS PRESENTED

1. Whether 21 U.S.C. § 360k(a) preempts common law claims challenging the safety or effectiveness of a medical device that the Food and Drug Administration has found to be safe and effective and has approved for marketing pursuant to the premarket approval process under 21 U.S.C. § 360e(c).

2. Whether petitioners adduced sufficient evidence to establish genuine issues of material fact respecting claims of fraud and breach of express warranty.*

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* Respondent Collagen Corporation has no parent corporation and no non-wholly owned subsidiaries.

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BRIEF IN RESPONSE TO THE PETITION

STATEMENT

1. Company history and regulatory background.

In the early 1970s, a group of biochemists and physicians at Stanford University developed a purified form of bovine collagen, a natural protein that provides structural support for skin, muscles, tendons, and bones. Together with other investors, they organized petitioner Collagen Corporation to manufacture and distribute collagen products to be used in various medical treatments. The principal product at issue in this case, Zyderm® Collagen Implant ("Zyderm"), is injected under the skin to correct or improve soft tissue deficiencies that arise from disease, trauma, or aging.

Zyderm is classified by the Food and Drug Administration ("FDA") as a Class III medical device subject to

regulation under the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360*l*. "Class III devices must generally undergo premarket approval (PMA) before the FDA will allow them into the marketplace." *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1339 (11th Cir. 1995), *cert. granted*, 116 S.Ct. 806 (January 19, 1996) (Nos. 95-754 and 95-886). The premarket approval process under 21 U.S.C. § 360e(c) (the "PMA process") is central to the statutory objective of ensuring that all medical devices on the market afford "reasonable assurance of safety and effectiveness." 21 U.S.C. § 360c(1)(c). Before the FDA approves a Class III device for marketing pursuant to the PMA process, it determines that the device is safe and effective with respect to (1) the persons for whose use the device is intended and (2) the conditions of use prescribed, recommended, or suggested in the labeling of the device. 21 U.S.C. § 360c(2).

The PMA process is not the exclusive means by which Class III medical devices enter the market. The MDA provides three alternative routes to marketability: premarket approval is not required for (1) devices on the market prior to the effective date of the MDA, (2) devices found to be substantially equivalent to a device already on the market, or (3) devices entitled to the investigational device exemption. *See* 21 U.S.C. §§ 360e(b)(1)(A) and (B), 360j(g). But premarket approval is the statutory paradigm, and "the MDA contemplates that most Class III devices will reach the market through the PMA process." *Lohr*, 56 F.3d at 1340; *see* 21 U.S.C. § 360e(a).

The PMA process entails an exhaustive investigation into safety and effectiveness. An applicant who seeks the FDA's approval to market a Class III device must provide:

> (A) full reports of all information, published or known to . . . the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture [and] processing . . . of such device;

(D) . . . adequate information to show that . . . such device fully meets [pertinent] performance standard[s] . . .;

(E) . . . samples of such device . . .;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information . . . as the [FDA] . . . may require.

21 U.S.C. § 360e(c)(1).

The application for premarket approval also must include, *inter alia*, a "general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended," an "explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device," and a "description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended." 21 C.F.R. § 814.20(b)(3). The application must be periodically updated "with new safety and effectiveness information learned about the device from ongoing or completed studies." 21 C.F.R. § 814.20(e).

A completed application is reviewed by a panel of experts. 21 U.S.C. § 360e(c)(2). After considering the panel's report and recommendation, the FDA will grant the application only if it finds reasonable assurance (1) that the device is safe and effective with respect to both the persons for whose use the device is intended and the

conditions of use prescribed, recommended, or suggested in its labeling, (2) that the manufacturing and processing method and facilities are satisfactory, and (3) that the proposed labeling is not false or misleading in any manner. 21 U.S.C. §§ 360c(2) and 360e(d)(2); *see also* 21 C.F.R. § 814.44.

Collagen filed an application with the FDA for premarket approval of Zyderm on April 30, 1980. Its application included, *inter alia,* the results of clinical testing in over five thousand human subjects. Erickson Aff., Ex. 2 ("Erickson Aff." refers to an affidavit submitted by Collagen in support of summary judgment). Following more than one year of detailed investigation, the FDA found Zyderm to be safe and effective and approved it for marketing. 46 Fed. Reg. 46394 (1981). The FDA's approval order for Zyderm set forth numerous "conditions of approval," including the following:

> *Before making any change that may affect the safety or effectiveness* of the device, [Collagen must] submit a supplemental PMA for review and approval by FDA. Such changes include, but are not limited to:
>
> (1) new indications for use;
>
> (2) labeling changes;
>
> (3) changes in manufacturing facilities, methods or quality control procedures, and involvement of new subcontractors, suppliers, or distributors;
>
> (4) changes in sterilization procedures;
>
> (5) changes in packaging;
>
> (6) changes in the performance or design specifications, circuits, parts, components, accessories, ingredients, or physical layout of the device.

Erickson Aff., Ex. 10 (emphasis in original). In 1985, the FDA issued a similar approval order, with similar conditions, for the marketing of Zyplast® Collagen Implant ("Zyplast"), a form of Zyderm that is cross-linked with glutaraldehyde. *Id.*, Ex. 36.

Collagen has marketed Zyderm since 1981, and Zyplast since 1985, as prescription-only medical devices, strictly in accordance with the conditions and other requirements imposed by the FDA. During this time, and as required by regulation, Collagen has furnished the FDA with information about "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device" and "[r]eports in the scientific literature concerning the device." 21 C.F.R. § 818.84(b)(2). In 1991, after ten years of clinical experience, the FDA undertook a review of the record of Zyderm's performance. Erickson Aff. at 5. At the conclusion of that review, the FDA reaffirmed its finding of safety and effectiveness. *Id.*

2. Proceedings in this case.

In 1988, petitioner Barbara Mitchell received a series of injections of Zyderm and Zyplast as treatment for facial wrinkles. She claims that subsequent to her treatment she developed an autoimmune disease and that Zyderm or Zyplast caused this disease. In 1993, she and her husband brought suit against Collagen in an Indiana state court, alleging negligence, strict liability, mislabeling and adulteration, fraud, and breach of warranty. Collagen removed the case to the United States District Court for the Northern District of Indiana, where jurisdiction rested on 28 U.S.C. § 1332.

The district court granted summary judgment for Collagen on the ground that petitioners' tort claims were precluded by the MDA preemption statute, 21 U.S.C. § 360k (a). That statute bars the states from imposing, with respect to a medical device, "any requirement—(1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." The district court determined, following *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 506 U.S. 917 (1992),

that (1) state tort law imposes "requirements" within the meaning of the MDA preemption statute and (2) that enforcement of the particular tort laws invoked by petitioners would result in the imposition of state requirements different from or in addition to the federal requirements applicable to Zyderm under the MDA. Pet. App. 45-69.

The Seventh Circuit affirmed. Drawing support from the reasoning of a majority of the Justices in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the court first determined that "[t]he phrase 'any requirement' in 21 U.S.C. §360k(a) is broad enough to include at least some common law causes of action within the statute's preemptive scope." Pet. App. 13. The court observed, moreover, that its holding in this regard was consistent with that of "every circuit that has considered the question." *Id.* at 12 and n.3 (citing decisions from the First, Third, Fifth, Eighth, Ninth, and Eleventh Circuits).

In reaching this conclusion, the Seventh Circuit rejected the Mitchells' contention that an FDA regulation, 21 C.F.R. § 808.1(d), exempts state common law from preemption. That regulation construes the MDA preemption statute as "not preempt[ing] State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices . . . ." Expressly agreeing with the decision of the Third Circuit in *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994), the court explained:

> the regulation does not speak to common law claims; its reference to requirements of "general applicability" is not to common law causes of action but to electrical codes and the U.C.C.—positive enactments of law. Indeed, section 808.1(d), listing various state requirements that are not preempted by the statute, is noticeably silent on the matter of state tort claims when read in its entirety . . . . [I]f we were to give

> 21 C.F.R. § 808.1(d) the breadth which the Mitchells urge that we give it, we would contradict squarely the manifest intent of the statute which, as we have already noted, clearly evidences a congressional intent to preempt [at least] some common law causes of action.

Pet. App. 16.

The Seventh Circuit next turned to the Mitchells' contention that Zyderm is not subject to any federal "requirement" within the meaning of the MDA preemption statute. The Mitchells relied upon another paragraph of 21 C.F.R. § 808.1(d), providing that "state or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." Expressly agreeing with the reasoning of the Eleventh Circuit in *Lohr*, the court "conclude[d] that the premarket approval process constitutes a 'specific requirement' for purposes of 21 C.F.R. § 808.1(d)." Pet. App. 20; *see also id.* at n.6 (pointing out that, in addition, the First, Third, Fifth, and Eighth Circuits also have reached the same conclusion).

The Seventh Circuit then proceeded to "analyze each of the Mitchells' claims against Collagen to determine whether they would add requirements 'different from, or in addition to,' the PMA process or other FDA requirements and therefore be preempted." Pet. App. 21-22. Turning first to the Mitchells' negligence and strict liability claims, the court "agree[d] with several other circuits which have considered the issue that, with respect to a Class III device that has undergone the PMA process, such claims are preempted because they undoubtedly would add requirements 'different from, or in addition to,' those set forth in the MDA." *Id.* at 23 and n.7 (citing cases).

With respect to the Mitchells' claim of mislabeling and adulteration, the Seventh Circuit held that "[t]o the extent this allegation charges that Zyderm, despite con-

formity to the FDA's premarket approval process, was mislabeled, misbranded, or adulterated, the . . . claim would be preempted for the [same] reasons." Pet. App. 25. On the other hand, even if the adulteration claim could be viewed as alleging that "Collagen [had] failed to meet the labeling and purity standards established *by* the PMA process," *id.* at 26 (emphasis in original), summary judgment was proper because Collagen demonstrated in the district court "not only that adulteration claims should be preempted per se, but also that no geninue issue of material fact existed with respect to the Mitchells' adulteration claim." *Id.* at 29.

The Mitchells asserted two distinct claims of fraud and misrepresentation: that Collagen had defrauded the FDA during the PMA process, and that Collagen had committed fraud in the course of marketing Zyderm. As to the Mitchells' "fraud on the FDA" theory, the Seventh Circuit agreed with the First Circuit in *Talbott v. C. R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, Feb. 16, 1996 (No. 95-1321), and the Third Circuit in *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 116 S. Ct. 67 (1995), that the MDA preemption statute "does not permit such a searching state inquiry into the inner workings of FDA procedures." Pet. App. 31. As to the claim of marketing fraud, the court noted that the Mitchells appeared to be contending that the FDA had approved fraudulent packaging and labeling; such a contention, the court held, was clearly preempted. *Id.* at 31. But even if, "giv[ing] the Mitchells the benefit of the doubt," *id.* at 32, their claims were construed as alleging that Collagen had departed from its FDA-approved packaging and labeling, summary judgment was proper: Collagen had introduced evidence showing that its advertising and promotional materials conformed to the FDA's requirements, and "[t]he Mitchells did not introduce affidavits, depositions, or other materials either to rebut Collagen's submissions or to demonstrate that there were genuine issues with respect to other promotional materials." *Id.* at 33.

The Mitchells had made a general allegation of breach of warranty without "specif[ying] what warranties were at issue nor what statements of warranty Collagen allegedly provided." Pet. App. 33-34. The Seventh Circuit agreed with the First, Third, Fifth, Eighth, and Eleventh Circuits that all claims of implied warranty are preempted. *Id.* at 34-35 and n.11. At the same time, the court agreed with the Third Circuit (and disagreed with the First Circuit) in holding that claims of express warranty are not preempted. *Id.* at 35-37. The court concluded, however, that "the Mitchells' summary judgment filings prevent them from benefitting from this analysis." *Id.* at 37. The court explained:

> the Mitchells never specified in the district court whether their claim was based upon implied or express warranties. Likewise, the Mitchells never pointed to any express warranty that Collagen allegedly violated. In response to Collagen's submission that there was no genuine issue of material fact with respect to their complaint against Collagen, the Mitchells introduced no affidavits, depositions, documents, or other evidence creating a genuine issue of fact as to the existence of any express warranty provided by Collagen. Accordingly, we must hold that the Mitchells failed to meet their burden at the summary judgment stage . . . .

Pet. App. 38.

DISCUSSION

This case involves three important issues concerning the application of the MDA preemption statute to Class III medical devices that the FDA has found to be safe and effective and has approved for marketing pursuant to the rigorous and comprehensive PMA process. The circuits are split over each of these issues, and the resulting conflicts should be resolved.

(1) The Seventh Circuit in this case, like the First, Second, Third, Fourth, Fifth, Sixth, Eighth, and Eleventh Circuits in other cases, holds that state common law

imposes "requirements" within the meaning of the MDA preemption statute and thus is subject to preemption. *See, e.g., Mendes v. Medtronic, Inc.*, 18 F.3d 13, 16 (1st Cir. 1994); *Becker v. Optical Radiation Corp.*, 66 F.3d 18, 20 (2d Cir. 1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir.), *cert. denied*, 115 S. Ct. 429 (1994); *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 397-98 (4th Cir. 1995); *Reeves v. Acromed Corp.*, 44 F.3d 300, 304 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995); *Martin v. Telectronics Pacing Systems, Inc.*, 70 F.3d 39, 41 (6th Cir. 1995); *National Bank of Commerce v. Kimberly-Clark Corp.*, 38 F.3d 988, 991 (8th Cir. 1994); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335, 1342 (11th Cir. 1995), *cert. granted*, 116 S. Ct. 806 (January 19, 1996) (Nos. 95-754 and 95-886). The Ninth Circuit, however, has held that state common law does not impose "requirements" and thus falls outside the scope of the MDA preemption statute. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1460-61 (9th Cir. 1995). Collagen intends to file a petition for writ of certiorari in *Kennedy*, but this Court presumably will resolve the conflict in *Medtronic*.

(2) The Seventh Circuit in this case, like the First, Third, Fifth, and Eighth Circuits in other cases, holds that the requirements imposed by the FDA in connection with the PMA process also are "requirements" within the meaning of the MDA preemption statute and thus give rise to preemption. *See, e.g., King v. Collagen Corp.*, 983 F.2d 1130, 1134 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1324 (3d Cir), *cert. denied*, 116 S. Ct. 67 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421-22 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993); *Martello v. Ciba Vision Corp.*, 43 F.3d 1167, 1169 (8th Cir. 1994), *cert. denied*, 115 S. Ct. 2614 (1995). On the other hand, the Ninth Circuit in *Kennedy* held that the PMA process itself is not a "requirement" under the MDA preemption statute and, in addi-

tion, appeared to believe that the PMA process does not impose any "requirements" either. *See* 67 F.3d at 1459-60. This issue is not directly before the Court in *Medtronic,* which involves a medical device granted premarket clearance by the FDA pursuant to the more abbreviated notification procedure under 21 U.S.C. § 360 (k) (the "510(k) process"). If this Court in *Medtronic* concludes, however, that the 510(k) process imposes "requirements," then the same result for the PMA process follows *a fortiori.* But if the Court does not reach that issue or that conclusion in *Medtronic,* the existing conflict with respect to the PMA process will remain. This conflict could appropriately be resolved either in *Kennedy* or in this case.

(3) The Seventh Circuit in this case, like the Third Circuit in *Michael,* 43 F.3d at 1325, holds that claims based on a common law theory of express warranty are not barred by the MDA preemption statute. The First and Sixth Circuits hold, to the contrary, that express warranty claims are preempted. *Talbott v. C. R. Bard, Inc.,* 63 F.3d 25, 29 (1st Cir. 1995), *petition for cert. filed,* Feb. 16, 1996 (No. 95-1321); *Martin,* 70 F.3d at 42. The Fourth Circuit holds that express warranty claims are preempted to the extent that they are based on FDA-mandated labeling, packaging, or advertising but are not preempted otherwise. *Duvall,* 65 F.3d at 400. This issue is not presented in *Medtronic,* and the existing conflict therefore will survive the decision in that case. Because the Seventh Circuit ruled against the Mitchells' express warranty claim on another ground, however, the MDA preemption statute provides only an alternative basis for affirming that ruling; this Court thus might not have occasion to reach the preemption issue in this case. *Kennedy* provides a better vehicle for deciding this issue.

I. WITH THE EXCEPTION OF ITS ANALYSIS OF EXPRESS WARRANTY CLAIMS, THE DECISION BELOW IS CORRECT WITH RESPECT TO PREEMPTION UNDER THE MDA.

a. The Seventh Circuit correctly held that "[t]he phrase 'any requirement' in 21 U.S.C. § 360k(a) is broad enough to include at least some common law causes of action within the statute's preemptive scope." Pet. App. 13. This issue has been fully briefed to the Court in *Medtronic*, and for the present Collagen simply adopts the reasoning of the court below and that of Medtronic and its supporting *amici curiae* with respect to that issue.

b. The detailed and demanding PMA process both encompasses and imposes requirements giving rise to preemption under the MDA preemption statute. In arguing the contrary, the Mitchells rely upon 21 C.F.R. § 808.1 (d), which provides that "state or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." This reliance is doubly misplaced. The FDA itself has explained that for Class III medical devices like Zyderm "the counterpart FDA requirement [is] the requirement that the product have premarket approval." 43 Fed. Reg. 18661, 18664 (1978). Beyond that, and as the facts of this case demonstrate, the marketing approval order generated by the PMA process imposes numerous "specific requirements applicable to [the] particular device." *See* p. 4, *supra*. The Seventh Circuit plainly was correct in holding that Zyderm is subject to federal "requirements" within the meaning of the MDA preemption statute.

c. Claims based upon theories of strict liability, negligence, mislabeling, misbranding, adulteration, fraud, misrepresentation, and implied warranty all, at bottom, are claims that the medical device should have been designed, manufactured, packaged, labeled, and advertised in a

manner different from that both explicitly approved by the FDA upon finding the device safe and effective and explicitly required by the FDA as a condition of continued marketability. The central purpose of the MDA preemption statute is to protect manufacturers of medical devices from conflicting demands of this sort. With the exception of the Ninth Circuit's aberrant decision in *Kennedy*, every circuit that has reached this issue has so held. The decision of the Seventh Circuit on this issue was, once again, plainly correct.

d. The Seventh Circuit erred, however, in holding that the Mitchells' express warranty claim (if, indeed, the claim can be so characterized) is not preempted. The Mitchells alleged, with no elaboration or supporting evidence, that Collagen had "warranted and represented . . . that [Zyderm was] safe for [its] intended use and purpose." Pet. App. 33. To prevail on the merits of that claim, the Mitchells would have to persuade a court or jury to find, *inter alia*, that Zyderm is not safe. Such a finding would directly contradict the FDA's explicit determination that Zyderm is safe and effective. Positing liability on that ground, moreover, would impose a state-law based requirement that Collagen change its manufacturing or other processes so as to make Zyderm "safe" by state-law standards. It would, in other words, impose state requirements different from, or in addition to, the federal requirements imposed under the MDA. That result is expressly prohibited by the MDA preemption statute.

II. THE JUDGMENT BELOW WAS CORRECT.

The Seventh Circuit correctly determined that the Mitchells had not adduced sufficient evidence relating to their claims of fraud and express warranty to survive summary judgment. The Mitchells contest that holding, which of course was rooted in the particular summary judgment record of this case. But the Mitchells' contentions are insubstantial, and the narrow record-based issues

that they seek to raise do not, in any event, warrant review by this Court.

With respect to the allegation of fraud, it is apparent that the Mitchells sought to change the character and purported factual basis of their fraud claim on appeal, shifting their attack from Collagen's packaging and labeling to its advertising and promotional materials. *See* Pet. App. 31-32. But in moving for summary judgment in the district court, Collagen had demonstrated that its advertising and promotional materials, as well as its packaging and labeling, were subject to federal constraints and were in compliance with federal requirements. *Id.* at 33 and n.10. The Mitchells made no effort to rebut this showing. The Seventh Circuit correctly held that, on this record, the Mitchells' fraud claim was preempted.

The Mitchells' express warranty claim also was an apparent afterthought, asserted for the first time on appeal. *See* Pet. App. 38. The Seventh Circuit understandably was of the view that because the Mitchells had failed to specify or support such a claim in the district court in response to Collagen's submission that their complaint raised no genuine issues of material fact, "summary judgment was proper even though [in the court's view] such [express warranty] claims are not preempted by the MDA." *Id.* This holding does not warrant further review. Furthermore, as Collagen argued below, to the extent that the Mitchells' claim can be construed as alleging a breach of express warranty, it is barred by state law on two separate grounds: (1) there was no privity of contract between Collagen and the Mitchells, as required by Indiana law, *see, e.g., DeHoyos v. John Mohr & Sons,* 629 F. Supp. 69, 80 (N.D. Ind. 1984), *aff'd sub nom. Black v. Henry Pratt Co.,* 778 F.2d 1278 (7th Cir. 1985); (2) the Mitchells' action was not begun within the four-year Indiana statute of limitations for express warranty claims, *see Ferdinand Furniture Co. v. Anderson,* 399 N.E.2d 799, 802 (Ind. App. 1980).

CONCLUSION

The petition should be held pending disposition first of *Medtronic* and then of *Kennedy*; it should then be granted if, and only to the extent that, it presents preemption issues left unresolved by this Court's disposition of those cases.

Respectfully submitted,

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